REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

Upon entry of this amendment, claims 51 – 119 are pending. Claims 51, 84, and 85 are amended and claims 118 and 119 are added.

Claims 51 and 84 are amended to replace the phrase "poorly soluble drug" with "the drug has a solubility in said aqueous dispersion of less than about 10 mg/mL." Support for this amendment can be found, for example, on page 25, lines 1 – 3, of the specification. Claim 84 is also amended to define the term "pMDI" as a "pressurized metered dose inhaler." *See* page 2, line 20, of the specification. Similarly, claim 85 is amended to define "non-CFC" as a "non-chlorofluorocarbon." *See* page 5, line 4, of the specification. Support for new claims 118 and 119, which recite specific drugs, can be found in Examples 1 and 2 (beclomethasone dipropionate); Examples 3 and 4 (naproxen); Examples 5, 8A, and 9B (triamcinclone acetonide); Examples 6 and 9A (budesonide); and Examples 7, 7A, and 7B (an anti-emetic).

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Restriction Requirement

Applicants acknowledge that the Examiner has made the restriction requirement final. Applicants will cancel claims drawn to non-elected subject matter upon notice of allowable subject matter. Upon entry of this Amendment, claims 51 – 64, 79 – 81, 84 – 101, 118, and 119 are under examination and claims 65 – 78, 82, 83, and 102- 117 are withdrawn from consideration.

III. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 51 – 64, 79 – 81, and 84 – 101 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite on four grounds. Office Action at page 2. Applicants respectfully traverse this ground for rejection.

A. The Examiner's First Ground of Rejection

1. Rejection for Recitation of the Term "Essentially"

The Examiner first alleged that the term "essentially" is vague. In support of this rejection, the Examiner stated that it is not clear whether "essentially" refers to all claimed aerosol droplets or just a few.

2. The Specification Guides a Person of Ordinary Skill in the Art to Determine That Essentially Each Claimed Droplet Contains Nanoparticulate Drug

MPEP § 2173.05(b) specifically states that the use of the term "essentially" is definite where the specification contains guidelines and examples that are sufficient to enable a person of ordinary skill in the art to "draw a line" that defines the element to which the term "essentially" refers. Here, the term "essentially" in claims 51 and 84 cannot be read in isolation, but must be read in context, which is the totality – not a few – of individual aerosol droplets that contain at least one nanoparticulate drug particle.

The specification is replete with examples showing that aerosolized droplets of a distribution of sizes all contain drug nanoparticles. *See* Tables I, II, and III in the specification. It would be an impractical standard to require Applicants to specify a number of aerosol droplets containing drug nanoparticles, where the examples clearly demonstrate that aerosol droplets of a certain size, considered in the *aggregate*, contain nanoparticulate drug particles. Thus, the claims are not indefinite by reciting that "essentially" *each* droplet comprises at least one drug nanoparticle. Accordingly, this rejection should be withdrawn.

B. The Examiner's Second Ground of Rejection

1. Rejection for Recitation of "the Drug" and "Therapies"

The claims stand rejected as being allegedly unclear because Markush claims refer to both "drugs" and "therapies."

2. The Term "Therapies" is Synonymous With "Drug Classes"

Within the ambit of 35 U.S.C. § 112, second paragraph, Applicants are free to define their invention in the claims using whatever terms they wish to the extent that those terms are not

repugnant to the art-accepted definitions. *See* MPEP § 2173.01. Here, Applicants have simply chosen to define a drug as being a member of one of several drug classes, or, equivalently, drug therapies. The term "therapies" is recited in claims 52 and 86 with other classes of drugs. In any event, one of ordinary skill in the art would know that the term "therapies" encompasses drug classes because the specification specifically discloses this definition at page 25, lines 9 – 16.

Aside from pointing out a purported semantic difference between "drug" and "therapies," the Examiner has not advanced any reason why the term "therapies" is unclear. Accordingly, Applicants respectfully request that this rejection be withdrawn.

C. The Examiner's Third Ground of Rejection

1. Rejection for the Recitation of "Poorly Soluble"

The claims stand rejected as being allegedly indefinite because the term "poorly soluble" does not refer to a medium in which solubility of a drug is determined.

2. The Claims Are Clear Because They Set Forth an Objective Measure of Drug Solubility

The Examiner's rejection appears to hinge on a purported difficulty in determining claim scope based upon the absence of a recitation of a drug medium. Naturally, the solubility of a given drug is going to vary in different liquid dispersion mediums, regardless of whether the liquid dispersion medium is aqueous or organic. The only requirement is that the drug is poorly soluble in the liquid dispersion medium of choice. Nonetheless, and solely to advance prosecution, claims 51 and 84 as amended recite that the solubility of the drug in the liquid dispersion medium is less than about 10 mg/mL. Withdrawal of this ground for rejection is respectfully requested.

D. The Examiner's Fourth Ground for Rejection; Recitation of the Terms "pMDI" and "CFC"

The claims were rejected as being allegedly indefinite because the terms "pMDI" and "non-CFC" are not recited as their "full terms." While the meaning of these terms should be abundantly clear to a person of ordinary skill in the art upon a reading of the specification, claims 84 and 85 as amended define these terms. Withdrawal of this ground for rejection is respectfully requested.

IV. Conclusion

Applicants respectfully request reconsideration of this application in view of the above amendments and remarks. This application is now in condition for allowance and early notice to that effect is respectfully solicited.

Should the Examiner have any questions or comments regarding the pending application or this Amendment, the Examiner is requested to call the undersigned at 202-672-5538.

If there are any fees due in connection with the filing of this Amendment, please charge the fees to our Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date July 29, 2002

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Version of Claims with Markings to Show Changes Made

51. (Once amended) An aerosol composition of an aqueous dispersion of nanoparticulate drug particles, wherein:

(a) essentially each droplet of the aerosol comprises at least one nanoparticulate [poorly soluble]drug particle, wherein the drug has a solubility in said aqueous dispersion of less than about 10 mg/mL;

(b) the droplets of the aerosol have a mass median aerodynamic diameter (MMAD) less than or equal to about 100 microns; and

(c) the nanoparticulate drug particles comprise a poorly soluble drug, have an effective average particle size of less than about 1000 nm, and have a surface modifier adsorbed on the surface of the drug.

84. (Once amended) A nanoparticulate aerosol composition for use in a propellant-based pressurized metered-dose inhaler (pMDI) comprising:

(a) a nanoparticulate [poorly soluble]crystalline drug, wherein the drug has a surface modifier adsorbed on the surface thereof, [and]wherein the drug has an effective average particle size of less than about 1000 nm, and wherein the drug has a solubility of less than about 10 mg/mL;

(b) essentially each droplet of the aerosol comprises at least one nanoparticulate drug particle, wherein the droplets of the aerosol generated by the pMDI have a diameter of less than or equal to about 100 microns, and

(c) a non-aqueous propellant.

85. (Once amended) The aerosol composition of claim 84, wherein the propellant is a non-chlorofluorocarbon (non-CFC) propellant.